

JPW



FULBRIGHT & JAWORSKI L.L.P.

A REGISTERED LIMITED LIABILITY PARTNERSHIP

600 CONGRESS AVENUE, SUITE 2400

AUSTIN, TEXAS 78701-3271

WWW.FULBRIGHT.COM

STEVEN L. HIGHLANDER
PARTNER
SHIGHLANDER@FULBRIGHT.COM

DIRECT DIAL: (512) 536-3184
TELEPHONE: (512) 474-5201
FACSIMILE: (512) 536-4598

September 9, 2004

CERTIFICATE OF MAILING 37 C.F.R 1.8	
I certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:	
September 9, 2004	
Date	Steven L. Highlander

MS AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/810,063 entitled "ADENOVIRUS REPLICATION-COMPETENT VECTORS EXPRESSING TRAIL" – William Wold et al.*
Our reference: INGN:106US

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references B1 and C1-C50.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INGN:106US.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Steven L. Highlander
Reg. No. 37,642

SLH/kmv
Encl.: as noted



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
William Wold *et al.*

Serial No.: 10/810,063

Filed: March 26, 2004

For: ADENOVIRUS REPLICATION-
COMPETENT VECTORS EXPRESSING
TRAIL

Group Art Unit: 1653

Examiner: Unknown

Atty. Dkt. No.: INGN:106US

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:	
September 9, 2004	
Date	Steven L. Highlander

INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

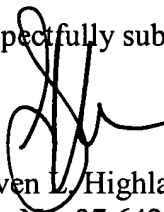
In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INGN:106US.

Applicants respectfully request that the listed documents be made of record in the present case.

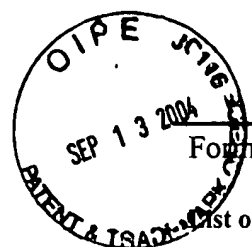
Respectfully submitted,



Steven L. Highlander
Reg. No. 37,642
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: September 9, 2004



Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

INGN:106US

Serial No.

10/810,063

Applicant

William Wold *et al.*

Filing Date:

March 26, 2004

Group:

1653

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 01/04282	1/18/01	PCT			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Alemaný <i>et al.</i> , "Replicative adenoviruses for cancer therapy," <i>Nat. Biotechnol.</i> , 18:723-727, 2000.
	C2	Arai <i>et al.</i> , "Gene transfer of Fas ligand induces tumor regression in vivo," <i>Proc. Natl. Acad. Sci., USA</i> , 94:13862-13867, 1997.
	C3	Armeanu <i>et al.</i> , "Adenoviral gene transfer of tumor necrosis factor-related apoptosis-inducing ligand overcomes an impaired response of hepatoma cells but causes severe apoptosis in primary human hepatocytes," <i>Cancer Res.</i> , 63:2369-2372, 2003.
	C4	Ashkenazi <i>et al.</i> , "Safety and antitumor activity of recombinant soluble Apo2 ligand," <i>J. Clin. Invest.</i> , 104(2):155-162, 1999.
	C5	Bischoff <i>et al.</i> , "An adenovirus mutant that replicates selectively in p53-deficient human tumor cells," <i>Science</i> , 274(5286):373-376, 1996.
	C6	Bodmer <i>et al.</i> , "Cysteine 230 is essential for the structure and activity of the cytotoxic ligand TRAIL," <i>J. Biol. Chem.</i> , 275(27):20632-20637, 2000.
	C7	Djeha <i>et al.</i> , "Combined adenovirus-mediated nitroreductase gene delivery and CB1954 treatment: a well-tolerated therapy for established solid tumors," <i>Mol. Ther.</i> , 3:233-240, 2001.
	C8	Doronin <i>et al.</i> , "Overexpression of the ADP (E3-11.6K) protein increases cell lysis and spread of adenovirus," <i>Virology</i> , 305:378-387, 2003.

25412059.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)	Atty. Docket No. INGN:106US	Serial No. 10/810,063
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant William Wold <i>et al.</i>	
	Filing Date: March 26, 2004	Group: 1653
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C9	Doronin <i>et al.</i> , "Tumor-specific, replication-competent adenovirus vectors overexpressing the adenovirus death protein," <i>J. Virol.</i> , 74(13):6147-6155, 2000.
	C10	Doronin <i>et al.</i> , "Tissue-specific, tumor-selective, replication-competent adenovirus vector for cancer gene therapy," <i>J. Virol.</i> , 75(7):3314-3324, 2001.
	C11	Freytag <i>et al.</i> , "A novel three-pronged approach to kill cancer cells selectively: concomitant viral, double suicide gene, and radiotherapy," <i>Human Gene Ther.</i> , 9:1323-1333, 1998.
	C12	Goldberg <i>et al.</i> , "Global effects of anchorage on gene expression during mammary carcinoma cell growth reveal role of tumor necrosis factor-related apoptosis-inducing ligand in anoikis," <i>Cancer Res.</i> , 61:1334-1337, 2001.
	C13	Goodrum and Omelles, "p53 status does not determine outcome of E1B 55-kilodalton mutant adenovirus lytic infection," <i>J. Virol.</i> , 72(12):9479-9490, 1998.
	C14	Griffith and Broghammer, "Suppression of tumor growth following intralesional therapy with TRAIL recombinant adenovirus," <i>Mol. Ther.</i> , 4(3):257-266, 2001.
	C15	Griffith <i>et al.</i> , "Adenoviral-mediated transfer of the TNF-related apoptosis-inducing ligand/Apo-2 ligand gene induces tumor cell apoptosis," <i>J. Immunol.</i> , 165(5):2886-2894, 2000.
	C16	Harada and Berk, "p53-independent and -dependent requirements for E1B-55K in adenovirus type 5 replication," <i>J. Virol.</i> , 73(7):5333-5344, 1999.
	C17	Harlow <i>et al.</i> , "Monoclonal antibodies specific for adenovirus early region 1A proteins: extensive heterogeneity in early region 1A products," <i>J. Virol.</i> , 55(3):533-546, 1985.
	C18	Haviv <i>et al.</i> , "Heat shock and heat shock protein 70i enhance the oncolytic effect of replicative adenovirus," <i>Cancer Res.</i> , 61:8361-8365, 2000.
	C19	Hawkins and Hermiston, "Gene delivery from the E3 region of replicating human adenovirus: evaluation of the E3B region," <i>Gene</i> , 81:142-148, 2001.
	C20	Horowitz, "Adenoviruses," In: <i>Fields Virology</i> , Field <i>et al.</i> (eds.), Lippencott-Raven, Philadelphia, 2301-2326, 1996.
	C21	Howe <i>et al.</i> , "Retinoblastoma growth suppressor and a 300-kDa protein appear to regulate cellular DNA synthesis," <i>Proc. Natl. Acad. Sci., USA</i> , 87:5883-5887, 1990.
	C22	Jones and Shenk, "Isolation of adenovirus type 5 host range deletion mutants defective for transformation of rat embryo cells," <i>Cell</i> , 17:683-689, 1979.

25412059.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. INGN:106US	Serial No. 10/810,063
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant William Wold <i>et al.</i>	
		Filing Date: March 26, 2004	Group: 1653
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C23	Kagawa <i>et al.</i> , "Antitumor activity and bystander effects of the tumor necrosis factor-related apoptosis-inducing ligand (TRAIL) gene," <i>Cancer Res.</i> , 61:3330-3338, 2001.
	C24	Khuri <i>et al.</i> , "A controlled trial of intratumoral ONYX-015, a selectively-replicating adenovirus, in combination with cisplatin and 5-fluorouracil in patients with recurrent head and neck cancer," <i>Nat. Med.</i> , 6:879-885, 2000.
	C25	Kim <i>et al.</i> , "ONYX-015: clinical data are encouraging," <i>Nat. Med.</i> , 4:1341-1342, 1998.
	C26	Krajcsi <i>et al.</i> , "Adenovirus replication-competent vectors expressing TRAIL," Department of Molecular Microbiology and Immunology, Saint Louis University Health Sciences Center.
	C27	Mariani and Krammer, "Differential regulation of TRAIL and CD95 ligand in transformed cells of T and B lymphocyte lineage," <i>Eur. J. Immunol.</i> , 28:973-982, 1998.
	C28	Martin and Berk, "Corepressor required for adenovirus E1B 55,000-molecular-weight protein repression of basal transcription," <i>Mol. Cell Biol.</i> , 19(5):3403-3414, 1999.
	C29	Nesterov <i>et al.</i> , "Elevated Akt activity protects the prostate cancer cell line LNCaP from TRAIL-induced apoptosis," <i>J. Biol. Chem.</i> , 276(14):10767-10774, 2001.
	C30	Ring, "Cytolytic viruses as potential anti-cancer agents," <i>J. General Virology</i> , 83:491-502, 2002.
	C31	Rogulski <i>et al.</i> , "In vivo antitumor activity of ONYX-015 is influenced by p53 status and is augmented by radiotherapy," <i>Cancer Res.</i> , 60:1193-1196, 2000.
	C32	Scaria <i>et al.</i> , "The E3-11.6K protein of adenovirus is an Asn-glycosylated integral membrane protein that localized to the nuclear membrane," <i>Virology</i> , 191:743-753, 1992.
	C33	Shenk In: <i>Fields Virology</i> , Field <i>et al.</i> (eds.), Lippencott-Raven, Philadelphia, 2265-2300, 1996.
	C34	Sheridan <i>et al.</i> , "Control of TRAIL-induced apoptosis by a family of signaling and decoy receptors," <i>Science</i> , 277(5327):818-821, 1997.
	C35	Shinoura <i>et al.</i> , "Highly augmented cytopathic effects of a fiber-mutant E1B-defective adenovirus for gene therapy of gliomas," <i>Cancer Res.</i> , 59:3411-3416, 1999.
	C36	Smith <i>et al.</i> , "Studies on the use of viruses in the treatment of carcinoma of the cervix," <i>Cancer</i> , 9(6):1211-1218, 1956.

25412059.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. INGN:106US	Serial No. 10/810,063
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant William Wold <i>et al.</i>	
		Filing Date: March 26, 2004	Group: 1653
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C37	Stewart and Burnett, "Adenovirus structure by x-ray crystallography and electron microscopy," In: <i>The Molecular Repertoire of Adenoviruses</i> , Doerfler <i>et al.</i> (ed.), Springer-Verlag, Heidelberg, Germany, 25-38, 1995.
	C38	Tollefson <i>et al.</i> , "Preparation and titration of CsCl-banded adenovirus stock," In: <i>Adenovirus Methods and Protocols</i> , Wold(ed.), Humana Press, Inc., Totowa, NJ, 1998.
	C39	Tollefson <i>et al.</i> , "The 11,600-M _w protein encoded by region E3 of adenovirus is expressed early but is greatly amplified at late stages of infection," <i>J. Virol.</i> , 66(6):3633-3642, 1992.
	C40	Tollefson <i>et al.</i> , "The adenovirus death protein (E3-11.6K) is required at very late stages of infection for efficient cell lysis and release of adenovirus from infected cells," <i>J. Virol.</i> , 70(4):2296-2306, 1996.
	C41	Tollefson <i>et al.</i> , "The E3-11.6-kDa adenovirus death protein (ADP) is required for efficient cell death: characterization of cells infected with adp mutants," <i>Virology</i> , 220:152-162, 1996.
	C42	Toth <i>et al.</i> , "Construction and characterization of E1-minus replication-defective adenovirus vectors that express E3 proteins from the E1 region," <i>Virology</i> , 301(1):99-108, 2002.
	C43	U.S. Patent Application Serial No. 09/351,778 filed July 12, 1999.
	C44	Walczak <i>et al.</i> , "Tumoricidal activity of tumor necrosis factor-related apoptosis-inducing ligand in vivo," <i>Nature Med.</i> , 5(2):157-163 1999.
	C45	Webb and Smith, "Viruses in the treatment of cancer," <i>Lancet</i> , 1:1206-1208, 1970.
	C46	White, "Regulation of apoptosis by adenovirus E1A and E1B oncogenes," <i>Semin. Virol.</i> , 8505-8513, 1998.
	C47	Wildner and Norris, "The role of the E1B 55 kDa gene product in oncolytic adenoviral vectors expressing herpes simplex virus-tk: assessment of antitumor efficacy and toxicity," <i>Cancer Res.</i> , 60:4167-4174, 2000.
	C48	Wildner, "In situ use of suicide genes for therapy of brain tumors," <i>Ann. Med.</i> , 31:421-429, 1999.
	C49	Wiley <i>et al.</i> , "Identification and characterization of a new member of the TNF family that induces apoptosis," <i>Immunity</i> , 3(6):673-682, 1995.
	C50	Wold <i>et al.</i> , "Adenovirus proteins that subvert host defenses," <i>Trends Microbiol.</i> , 2:437-443, 1994.

25412059.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.